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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,177	03/17/2004	Norman R. Wainwright	CHR-004	4155

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EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/803,177	WAINWRIGHT ET AL.	
	Examiner	Art Unit	
	Nathan A. Bowers	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,18,21,44,59 and 77* is/are pending in the application.

4a) Of the above claim(s) *15,18,21,44,59 and 77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *122704, 042805*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-14 in the reply filed on 17 July 2006 is acknowledged. The traversal is on the ground(s) that Groups I and II should be rejoined for purposes of further examination. This is not found persuasive because the method of Group II could be practiced with an apparatus other than that of Group I.

The requirement is still deemed proper and is therefore made FINAL.

It is believed that the previous Examiner failed to assign claim 21 to a specific group due to a typographical error. Independent claim 21 belongs to Group II because it is drawn to a method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Mahiout (WO 9953322).

With respect to claim 1, Mahiout discloses a cartridge for determining the presence of a microbial contaminant in a sample. The cartridge comprises a housing defining a fluid inlet port, an optical cell (5), and a conduit having a fluid contacting

surface for providing fluid flow communication between the fluid inlet port and the optical cell. Hemocyte lysate is disposed on a region (1) of the fluid contacting surface of the conduit, so that when a sample is applied to the fluid inlet port, the sample traverses the region and solubilizes the hemocyte lysate during transport to the optical cell. This is described on pages 1, 3-5, 8 and 9.

With respect to claims 2 and 3, Mahiout discloses the apparatus in claim 1 wherein a chromogenic substrate is disposed on a second region (2) downstream from the first region (1). This is described on pages 8 and 9 and is depicted in Figure 1.

With respect to claims 4-6, Mahiout discloses the apparatus in claim 1 wherein a preselected amount of bacterial endotoxin is disposed on the first region of the fluid contacting surface of the conduit. Mahiout teaches on pages 3 and 5 that the endotoxin reacts with lysate reagents in the first region, and is transported by flow through the cartridge.

2) Claims 1, 4-7 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Numazawa (EP 121868).

With respect to claim 1, Numazawa discloses a cartridge for determining the presence of a microbial contaminant in a sample. The cartridge comprises a fluid inlet port and a conduit. Numazawa indicates that the cartridge is transparent, and therefore is optically accessible throughout the length of the conduit. An opaque, white portion is positioned along the length of the cartridge to facilitate observation of color change. This is described on pages 2, 6 and 11. Pages 2-4 state that hemocyte lysate (Figure

1:2) is disposed on a region of the fluid contacting surface of the conduit so that when a sample is applied to the fluid inlet port, the sample traverses the region and solubilizes the hemocyte lysate during transport to the optical cell.

With respect to claims 4-6, Numazawa discloses the apparatus in claim 1 wherein bacterial endotoxins are disposed on the first region of the cartridge. This is disclosed on pages 2 and 3.

With respect to claim 7, Numazawa discloses a housing (Figure 7:8) defining a first fluid inlet port, a first optical cell, and a first conduit (1) having a fluid contacting surface for providing fluid flow communication between the first fluid inlet port and the first optical cell. A second fluid inlet port, a second optical cell, and a second conduit (1) having a first contacting surface for providing fluid flow communication between the second fluid inlet port and the second optical cell. First and second hemocyte lysate reagents (2) are disposed on first regions of the first and second conduits so that when sample is applied to each of the inlet ports, the sample will traverse the regions and solubilize the hemocyte lysate during transport. This multi-conduit system is described on page 10.

With respect to claims 12-14, Numazawa discloses the apparatus in claim 7 wherein bacterial endotoxins are disposed on the first regions of the cartridges. This is disclosed on pages 2 and 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3) Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mahiout (WO 9953322) in view of either Numazawa (EP 121868) or Parce (US 6306659).

Mahiout discloses the apparatus as previously described above, however only discloses the use of multiple fluidic conduits each comprising an inlet port, an optical cell and a reagents.

Numazawa discloses the apparatus as previously described. Numazawa discloses a multi-conduit system on page 10.

Parce discloses an apparatus for screening biological samples for the presence of a specific analyte. Parce states in column 2, line 65 to column 3, line 62 that a compound is delivered through a conduit on a microfluidic substrate where it is allowed to interact with various chemicals and reagents. Column 9, lines 17-55 indicate that, in this way, sample solutions are analyzed for the presence of bacteria and microorganisms. A detection window (116) is provided for optically interrogating the sample after it has been affected by the added reagents. Column 24, line 63 to column 25, line 36 and column 30, line 30 to column 31, line 24 state that a plurality of conduits are arranged in parallel for conducting identical reactions simultaneously.

Mahiout, Numazawa and Parce are analogous art because they are from the same field of endeavor regarding microorganism detection systems.

At the time of the invention, it would have been obvious to incorporate a plurality of conduits in the system proposed by Mahiout, wherein each conduit includes a fluid inlet port, an optical cell, and a region defined by hemocyte lysate. Numazawa and

Parce teach that parallel assay geometries are beneficial because they increase throughput and efficiency. This modification would only require the duplication of parts already disclosed as known by Mahiout, and therefore is considered to be an obvious improvement.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Tanaka (US 5550030), Michaels (US 4717658) and Lindsay (US 4301245) references teach the sate of the art regarding endotoxin specific assays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NAB

GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER